S.776

D. BISHOP

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DECLARATION OF POLICY

SEC. 2. (a) FINDINGS.—The Congress finds that—

(1) Human beings and the environment are exposed each year to a large and constantly growing number of chemical substances.

(2) Some chemical substances may pose an unreasonable risk to human health or the environment.

(3) The effective regulation of commerce in the

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interest of protecting human beings and the environment necessitates adequate data development with respect to, and necessary restrictions on, such substances.

(b) POLICY.—It is therefore declared to be the policy of the Congress in this Act that—

(1) adequate data should be developed with respect to chemical substances with respect to their effect on human health and the environment;

(2) such data development should be the responsibility of the persons who manufacture, import, or process such chemical substances;

(3) adequate authority should exist in the Environmental Protection Agency to regulate the manufacturing, importation, processing, and distribution in commerce of chemical substances which are found to pose an unreasonable risk to human health and the environment; ~~and~~

(4) such authority should be exercised in such a manner as to assure that technological innovation and commerce in chemical substances and products containing chemical substances are not unduly impeded while assuring that the manufacturing, importation, processing, or distribution in commerce of such substances do not pose an unreasonable risk to human health and the environment; and

(c) Congressional intent - It is the intent of Congress that the Administrator shall carry out this Act in a reasonable and prudent manner, and that he shall consider the environmental, [illegible] social impact of any action he proposes to

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Purpose & Supplement to Economic Impact Statement proposed as an Amendment to Sec. 6

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DEFINITIONS

SEC. 3. As used in this Act, the term—

(1) "Administrator" means the Administrator of the Environmental Protection Agency;

(2) "category of chemical substances" means a group of chemical substances the members of which are similar in molecular structure, in physical, biological or chemical properties, ~~in biological action, in use, or in mode of entrance into the human body or into the environment, or the members of which are in some other way suitable for classification as such for purposes of this Act,~~ except that the term does not mean all new chemical substances;

(3) "chemical substance" means (A) an organic or inorganic substance of a particular molecular identity, or a combination of such substances occurring as a result of a chemical reaction and not separated into its constituent components; (B) an uncombined radical or element; or (C) any mixture or category of mixtures specified by the Administrator in this discretion with respect to any provision of this Act. In specifying a mixture or category of mixtures under subparagraph (C) the Administrator shall consider the extent to which actions taken with respect to a mixture or mixtures so specified could be reasonably and as efficiently taken

insert "and which may have serious effects on the environment or the health and welfare of man"

5. the Administrator shall carry out this Act in a reasonable and prudent manner and that he shall consider EXT-0378028 in making health, economic and social impact of any action he

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with respect to the component chemical substances which comprise such mixture or mixtures;

(4) "commerce" means trade, traffic, transportation, communication, or exchange (A) between a place in a State and any place outside of such State, or (B) which affects trade, traffic, transportation, communication, or exchange described in subparagraph (A);

(5) "criteria for data development" means a prescription of (A) the manner in which data are to be developed with respect to the human health and environmental effects of a chemical substance; (B) any analysis that is to be performed on such data, and (C) any requirements to be met in the design of any test or study necessary to insure the reliability and adequacy of such data;

(6) "distribute in commerce" or "distribution in commerce" means to sell in commerce, to introduce or deliver for introduction into commerce, or to hold for sale or distribution after introduction into commerce, including use and disposal thereafter;

(7) "environment" includes man and the human environment, water, air, land, all living things therein, and the interrelationships which exist among and between these;

(8) "health and safety data" means data that relate to the effect of a chemical substance on human

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health and the environment, including data devcloped pursuant to health and safety studies. The term includes consumer or other individual correspondence regarding alleged adverse effects of a chemical substance on human health and the environment, reports of worker illness or injury allegedly related to exposure to a chemical substance, and complaints or other notices with respect to judicial or administrative proceedings initiated by local, State, or Federal authorities or other persons on account of any injury to human health and/or the environment that is alleged to have been caused by a chemical substance;

(9) "health and safety study" means a study of any effects of a chemical substance on human health and/or the environment. The term includes epidemiological studies, studies of occupational exposure to a chemical substance, toxicological studies, clinical studies, ecological studies, environmental monitoring studies, and all tests performed pursuant to this Act;

(10) "human health and the environment" should be read as if human health and/or the environment were set forth;

(11) "includes" should be read as if the phrase "but not limited to" were also set forth;

(12) "import" means to introduce, transport, or bring (A) into the United States from any place outside

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the United States; or (B) into the customs territory of the United States (as defined in general headnote 2 to the Tariff Schedules of the United States) from any place outside the customs territory of the United States;

(13) "importer" means a person who imports a chemical substance for distribution in commerce for commercial purpose;

(14) "manufacture" means to produce or manufacture;

(15) "manufacturer" means a person who manufactures a chemical substance;

(16) "mixture" means a combination of two or more chemical substances (A) that occurs naturally other than in the cause of the manufacture of chemical substance; or (B) that is produced by deliberate mixing according to plan but without intent to cause a chemical reaction and which does not result in a chemical reaction;

(17) "new chemical substance" means a chemical substance not included in the inventory compiled and published under section 8(b);

(18) "paragraph" means a paragraph of the subsection in which the term is used;

(19) "person" means an individual, corporation, partnership, association, State, municipality, or political subdivision of a State;

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(20) "process" means to prepare a chemical substance for distribution in commerce (A) in the same or in a different form, (B) in the same or in a different physical state, or (C) as part of another product;

(21) "processor" means a person who processes a chemical substance;

(22) "research and laboratory chemicals" means chemical substances manufactured, processed, or imported in small quantities solely for experimental use by professionally trained personnel;

(23) "section" means a section of this Act;

(24) "State" means a State, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Canal Zone, or American Samoa;

(25) "subparagraph" means a subparagraph of the paragraph in which the term is used;

(26) "subsection" means a subsection of the section in which the term is used;

(27) "test protocol" means a specific method or procedure to be followed in a test or tests to determine the effects on human health and the environment of the manufacture, processing, importing, or distribution in commerce of a chemical substance;

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(28) "United States" means all the States; and

(29) "unreasonable risk to human health and the environment" means ~~any risk~~ a significant level of risk associated with the manufacture, processing, importation, or distribution in commerce for a specific purpose ~~if such risk outweighs the~~ which is not outweighed by the benefits associated with such manufacture, processing, importation, or distribution in commerce. Any chemical substance which has been found, after appropriate evaluative tests (such as tests with animals) or other techniques, to have the potential to induce in human beings (1) cancer, (2) gene mutations, or (3) birth defects, shall be ~~considered~~ presumed to present an unreasonable risk to human health or the environment and the Administrator shall assess the benefits associated with such ~~take appropriate action under section 5(e), 6(a), or 7 with respect to any~~ manufacture, processing, importation, or distribution in commerce. ~~which results in exposure to human beings with respect to such substance~~ Unless the Administrator finds, by rule, that the benefits ~~associated~~ outweigh the risks associated with such manufacture, processing, importation, or distribution in commerce, outweighs the risks. Final action by the Administrator with respect to such chemicals ~~under section 6(a) or 7 (or rules issued by the Administrator finding that the benefits outweigh the risks with respect to such chemical substances)~~ shall be concluded as soon as feasible but not later than 3 years ~~after the date of enactment of this Act;~~ he shall take appropriate action under Sec 5(e), 6(a) or 7 with respect to any manufacture, processing, importation or distribution in commerce of such substance which results in levels of exposure to humans at levels which, with an appropriate Margin of Safety have been shown to induce (1) Cancer, (2) gene mutations or (3) birth defects. The Administrator shall assess the benefits of such chemicals and shall

(cont.) or promulgate his findings that the benefits with respect to such Substance outweigh the risks as soon as feasible but not later than 3 years after the date of enactment of this Act.

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CRITERIA FOR DATA DEVELOPMENT

SEC. 4. (a) GENERAL.—(1) *If the Administrator determines that—*

(A) because of known or anticipated manufacturing, processing, importing, or distribution in commerce of a chemical substance there is reason to believe that such substance may present an unreasonable risk to human health and the environment; and

(B) data development with respect to such risks as necessary would assist in making a determination of whether an unreasonable risk to human health and the environment does or does not exist; and is necessary in light of the possible risk measured against the possible costs of such data development then he shall, by rule, prescribe criteria for data development for such chemical substance. Such criteria shall include (i) the prescription of the human health and environmental effects for which data are required to be developed; (ii) the date by which such data should be submitted to the Administrator; and (iii) a requirement, subject to subsection (d), that such data be developed by each person who is or will be a manufacturer, a processor, or an importer of such substance.

(2) The Administrator shall require, pursuant to each rule issued under paragraph (1), that data be developed with respect to those human health and/or environmental effects which the Administrator specifies to be relevant with respect to the substance affected by such rule. In specifying such

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effects, as to which data development are required, the Administrator shall consider—

(A) the actual or estimated magnitude and duration of human exposure to such substance, and the possible consequences thereof with respect to human health; and

(B) the actual or estimated magnitude and duration of environmental exposure to such substance and the possible consequences thereof with respect to the environment.

The human health and environmental effects for which criteria for data development may be prescribed include carcinogenesis, mutagenesis, teratogenesis, behavioral disorders, acute toxicity, subacute toxicity, chronic toxicity, cumulative or synergistic effects, ecological effects, persistence, and any other effects that may cause an unreasonable risk to human health and the environment. The methodologies that may be prescribed in criteria for data development include epidemiology, serial, battery, or hierarchical tests; in vitro tests; and whole animal tests.

(3) From time to time, but not less than once each 12 months, the Administrator shall review the adequacy of the criteria for data development established under this subsection, and shall promulgate appropriate revisions thereof.

(b) NEW CHEMICAL SUBSTANCES.—Within 1 year

after the date of enactment of this Act, and from time to time thereafter, the Administrator shall by rule, prescribe criteria for data development, pursuant to subsection (a), that shall be applicable to new chemical substances and categories of new chemical substances.

(c) EXISTING CHEMICAL SUBSTANCES.—(1) Within 1 year after the date of enactment of this Act, the Administrator shall establish, and shall thereafter continually maintain, a list of ~~not less than 300~~ chemical substances, (other than new chemical substances) which are, in the Administrator's discretion, the highest priority candidates for the establishment of criteria for data development pursuant to subsection (a). From time to time thereafter, but not less than once every 2 years, the Administrator shall review and revise such list. Whenever the Administrator promulgates, or determines not to promulgate, a final rule pursuant to subsection (a), with respect to any chemical substance so listed, the Administrator shall delete such substance from such list and shall make any necessary additions to ~~maintain the size of~~ such list. Such list, and any revisions thereof, shall subject to section 14 (c) or (e) be published in the Federal Register together with the following information with respect to each chemical substance listed, to the extent that such information can be reasonably ascertained by the Administrator:

why not oppose the list?

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(A) the volume of production and use thereof;

(B) categories of use thereof;

(C) the magnitude, means, and duration of exposure to human beings and the environment that are associated with such substance;

(D) the extent to which such substance is physically or chemically similar to chemical substances with known adverse effects on human health and the environment; and

(E) any other property, or possible property, of such substance that may form a reasonable basis for placing such substance on such list.

(2) Within 1 year after the initial publication of the list under paragraph (1), the Administrator shall promulgate initial criteria for data development pursuant to subsection (a), with respect to any or all of the chemical substance which appear on such list. The Administrator may promulgate criteria for data development pursuant to subsection (a) for any other chemical substance.

(d) EXEMPTION.—(1) The Administrator may permit two or more persons who are required to develop data in accordance with subsection (a) to designate one such person, or a qualified and independent third party, to develop such data pursuant to a cost-sharing arrangement. If such an arrangement is made and approved by the Ad-

ministrator, the remaining such persons shall be exempted, pursuant to paragraph (2).

(2)(A) The Administrator shall exempt a person from the obligation to develop data in accordance with subsection (a), upon a determination that the data to be developed by such person would be duplicative of data previously received or which are in the process of being developed: Provided, That no exemption shall be granted before the person petitioning for such exemption—

(i) has demonstrated, to the satisfaction of the Administrator, that the chemical substance for which the exemption is requested (including any contaminants and/or byproduct impurities present in it) is equivalent to the chemical substance upon which the original test data was, or is in the process of being, developed; and

(ii) agrees to provide reimbursement, pursuant to subparagraphs (B) and (C).

(B) If the Administrator exempts a person from the obligation to develop data in accordance with subsection (a) because of the existence of previously submitted data or data which are in the process of being developed, and if such exemption takes effect during the reimbursement period for such data, as defined in subparagraph (C), the Administrator shall, as a condition of such exemption, order such person to provide fair and equitable reimbursement, on the basis of

market shares and other appropriate factors, by agreement or in an amount and subject to conditions determined under rules of the Administrator—

(i) to any person who previously submitted data or is developing such data, as a consequence of the availability of which such exemption is granted, for a portion of the relevant costs incurred by such person, and

(ii) to any other person who has previously been required under this paragraph to contribute with respect to such data.

An order under this paragraph shall be considered a final agency action for purposes of judicial review.

(C) For purposes of subparagraph (B), the reimbursement period for any previously submitted data or data in the process of being developed is a period—

(i) beginning on the earliest date on which a relevant exemption was granted under paragraph (1); and

(ii) ending 2 years after the data, with respect to which such exemption was granted, were submitted to the Administrator (or at the expiration of a period after such date equal in length to the period which the Administrator determines was necessary to develop the previously submitted data).

(3) In any case in which a person provides reimbursement, in accordance with paragraph (2), section 14(c) shall

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not be construed to prevent such person from having access to any data submitted as a result of the data development with respect to which such contribution or reimbursement was provided.

(e) SUBMISSION.—When the criteria for data development are satisfied by a person required to develop data in accordance with subsection (a), such data shall be submitted promptly, but not less than 10 days later, to the Administrator. The Administrator may require such a person to submit preliminary data or other information during the course of data development in accordance with subsection (a).

(f) NOTICE.—Upon the receipt of any data under this section, and subject to sections 14(c) or 14(e), the Administrator shall promptly publish a notice of such receipt in the Federal Register. Each such notice shall (1) identify the chemical substance for which data have been received; (2) list the uses or intended uses of such substance, and information required by the applicable criteria; and (3) describe the nature of the data developed. Such data shall be made available by the Administrator for examination by any person, except as otherwise provided in sections 14(c) or 14(e).

(g) PROCEDURE.—Rules issued under this section (and amendments thereto or repeals thereof) shall be promulgated pursuant to section 553 of title 5, United States Code. In

promulgating, amending, or repealing any criteria for data development or any other rule under this section (1) the Administrator shall give interested persons an opportunity for the oral presentation of data, views, or arguments, in addition to an opportunity to make written submission; and (2) a transcript shall be made of any oral presentation.

PREMARKET SCREENING OF CHEMICAL SUBSTANCES

SEC. 5. (a) GENERAL.—(1) Commencing 270 days after the date of enactment of this Act, a manufacturer or importer shall notify the Administrator of the planned manufacture or importation of a new chemical substance ~~(other than a mixture)~~, at least 90 days prior to the commencement of such manufacture or importation. Such notice shall be accompanied by any pertinent information referred to in section 8(a)(1), whether or not the Administrator has required the submission thereof under section 8(a)(1).

(2) The Administrator shall give priority attention to a chemical substance with respect to which information is received indicating that serious economic or other hardships are likely to result if there is any significant delay in manufacture or importation. If the Administrator finds that such a substance does not present an unreasonable risk to human health and the environment, he may reduce the number of days, after submission of such information, during which manufacture or importation may not occur. The Administra-

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tor shall promptly publish his findings and the basis therefor in the Federal Register.

(b) SUBMISSION OF DATA.—After the effective date of any criteria for data development issued under section 4(a), any manufacturer, processor, or importer of a new chemical substance that is covered by such criteria, and who first manufactures, processes, or imports such substance after such date, shall submit to the Administrator (in addition to the information required in subsection (a)), at least 90 days prior to such manufacture, processing, or importation, the data developed in accordance with such criteria.

(c) DATA AVAILABILITY.—The Administrator shall promptly publish in the Federal Register (subject to section 14(c) and 14(e)) the identity of each chemical substance for which a notice has been received under subsection (a) or (b), intended use or distribution of such substance, and a statement of the availability of any data and other information submitted.

(d) EXTENSION.—The Administrator may extend, for an additional period beyond the 90-day period referred to in subsection (a) or (b), the date after which a new chemical substance may be manufactured, processed, or imported for any particular distribution in commerce. Such additional period may not exceed 90 days and shall not be imposed except for good cause shown. Notice of any such extension, and the

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reasons therefor, shall be published in the Federal Register. Such an extension shall constitute a final action for purposes of judicial review.

(e) ORDERS.—(1)(A) If the Administrator finds, during the 90-day period referred to in subsection (a) or (b) or during any extension thereof, with respect to any new chemical substance for which notification is required under this section—

(i) that such new chemical substance is covered by criteria for data development promulgated under section 4(a), but that such criteria require additions or revisions with respect to such substance; or

(ii) that such new chemical substance is not covered by criteria for data development promulgated under section 4(a), but that such criteria should be established;

he shall issue an order in accordance with this subsection. Such an order shall appropriately prohibit or restrict the manufacture, processing, or distribution in commerce of such new chemical substance pending the completion of a rulemaking proceeding under section 4(a) and the submission of any data required thereunder, as described under subparagraph (B); shall contain a proposed rule under section 4(a); and shall be immediately effective.

(B) Upon the issuance of any order under subparagraph (A), the Administrator shall proceed with a rulemak-

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ing procedure as expeditiously as practicable under section 4 (a). During the course of, or upon the completion of, such rulemaking, the Administrator shall, if necessary, appropriately modify or rescind any order issued under subparagraph (A). If criteria for data development are established as a result of such rulemaking, any provision of such order restricting the manufacture, processing, or distribution in commerce of such substance shall remain in effect, unless modified or rescinded, pending the submission of such data to the Administrator and the completion of procedures described in subsection (b) or any extension imposed under subsection (d).

(2)(A) If the Administrator finds, during the 90-day period referred to in subsection (a) or (b) or during any extension thereof, with respect to any new chemical substance for which notification is required under this section, that a rule is appropriate under section 6(a), he shall issue an order in accordance with this subsection. Such an order shall appropriately prescribe such requirements as are authorized under section 6(a); shall contain a proposed rule under section 6(a); and shall be immediately effective.

(B) Upon the issuance of any order under subparagraph (A), the Administrator shall proceed with a rulemaking procedure as expeditiously as practicable under section 6(a). During the course of, or upon the completion of such rule-

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making, the Administrator shall, if necessary, appropriately modify or rescind any order issued under subparagraph (A).

(f) FAILURE TO ISSUE ORDER.—Unless the Administrator, within 90 days after the submission under subsection (a) or (b) of data and information with respect to a new chemical substance, or within such period as extended under subsection (d), issues an order under subsection (e) with respect to such substance, manufacturing, processing, or importing, as appropriate, may commence. ~~The Administrator's failure to issue such an order under subsection (e) is an action subject to judicial review in accordance with section 12(a).~~ Nothing in this subsection prohibits the Administrator from—

(1) promulgating a rule pursuant to section 6 or 4, with respect to such a substance, after such manufacturing, processing, or importing has commenced;

(2) taking action against any chemical substance which is found to be an imminent hazard pursuant to section 7; or

(3) taking any other action authorized by this Act.

(g) EXEMPTION.—(1) Upon petition, the Administrator shall exempt any person from the obligation to submit data under this section, if he determines that the submission of data by such person would be duplicative of data previously received: Provided, That no such determination

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shall be made before the person petitioning for such exemption has demonstrated, to the satisfaction of the Administrator, that the chemical substance for which the exemption is requested (including any contaminants and/or byproduct impurities present in it) is equivalent to the chemical substance upon which the original test data was developed and that reimbursement to the manufacturer, processor, or importer of such chemical substance as provided in paragraphs (2) and (3) shall be a condition precedent to the granting of any exemption to manufacturers, processors, or importers by the Administrator. Any person to whom an exemption has been granted under this paragraph shall not manufacture, process, or distribute in commerce such new chemical substance prior to the date after which such substance may be manufactured, processed, or imported under this section. Any chemical substance, or any manufacturer, processor, or importer thereof referred to in the preceding sentence, shall be subject to all the other provisions of this Act.

(2) If the Administrator exempts any person from submitting data under this section because of the existence of previously submitted data, and if such exemption takes effect during the reimbursement period for such data, as defined in paragraph (3), the Administrator shall order the exempt person to provide fair and equitable reimbursement,

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on the basis of market shares and other appropriate factors, by agreement or in an amount and subject to conditions determined under rules of the Administrator—

(A) to any person who previously submitted data, as a consequence of the availability of which such exemption is granted, for a portion of the relevant costs incurred by such person, and

(B) to any other person who has previously been required under this paragraph to contribute with respect to such data.

An order under this paragraph shall be considered a final agency action, for purposes of judicial review.

(3) For purposes of paragraph (2), the reimbursement period for any previously submitted data is a period—

(A) beginning on the earliest date (after submission of such data), on which a person who previously submitted data on which the exemption was based, was no longer prohibited from proceeding with the manufacture and distribution in commerce of a chemical substance to which such data applied, and

(B) ending two years after such date (or, if later, at the expiration of a period after such date equal in length to the period which the Administrator determines was necessary to develop the previously-submitted data).

(4) In any case in which a person provides reimburse-

ment in accordance with paragraph (2), section 14(c) shall not be construed to prevent such person from having access to any data submitted as a result of the data development with respect to which such reimbursement was provided.

(h) SIGNIFICANT NEW USE.—(1) Within 6 months after the date of enactment of this Act, and from time to time thereafter, the Administrator shall, by rule, establish criteria defining a significant new distribution in commerce of a chemical substance. In establishing such criteria, the Administrator shall take into account—

(A) projected volume of production;

(B) projected category or categories or uses;

(C) projected increase in magnitude and duration of human and environmental exposure;

(D) route or routes of exposure of human beings or of the environment that are attributable to such significant new use; and

(E) the human health and environmental effects thereof.

(2) A chemical substance may not be manufactured or imported for a use that is identified by the Administrator, in a rule, as a significant new distribution in commerce, unless, at least 90 days prior to such manufacture or importation, the person intending to manufacture or import such substance for such use submits a notice of his intention to do

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so and any data required to be developed under section 4(a) to the Administrator. Any such use of such substance shall be subject to all of the provisions of this section.

(i) SPECIAL EXEMPTION.—The Administrator may, upon application and by rule, exempt any person from the foregoing requirements of this section for the purpose of permitting such person to manufacture, process, import or distribute in commerce a new chemical substance to which a rule under section 4(a) is applicable for test marketing purposes or specially limited purposes (1) upon a showing by such person that such activity will not pose an unreasonable risk to human health and/or the environment and (2) under such restrictions as the Administrator considers appropriate.

HAZARDOUS CHEMICAL SUBSTANCES

SEC. 6. (a) GENERAL.—If the Administrator determines that a rule with respect to a chemical substance is necessary to protect against an unreasonable risk to human health and the environment, he shall prescribe such a rule under this section. Such a rule shall impose one or more of the following types of requirements to the extent necessary to protect against any such risk:

(1) Requirements (A) prohibiting the manufacturing, processing, importing, or distribution in commerce of the chemical substance involved, or (B) limiting the amount of such substance which may be manufactured, processed, imported or distributed in commerce.

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(2) Requirements (A) prohibiting the manufacturing, processing, importing, or distribution in commerce of the chemical substance involved for a particular distribution in commerce, or (B) limiting the amount of, or regulating the conditions under which, such substances may be manufactured, processed, imported and/or distributed in commerce for such particular distribution.

(3) Requirements mandating that the chemical substance involved, or an article containing such substance, be marked with or accompanied by clear and adequate warnings and instructions with respect to its use or disposal, in such form and bearing such content as the Administrator determines to be appropriate: Provided, That the Administrator shall consider the extent to which it is required to be marked under any other Federal law so that uniform markings may be developed to the maximum extent practicable.

(4) Requirements mandating that persons subject to requirements described in paragraphs (1), (2), or (3), make and retain records, and monitor or conduct tests, which are reasonable and necessary to assure compliance with such requirements.

The Administrator shall, in addition, by rule, direct manufacturers, importers, and processors of chemical substances to make and retain records of the processes used to manu-

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facture or process such substances and to monitor or conduct tests necessary to determine whether such substances, as manufactured, imported, or processed by them, are adulterated (within the meaning of subsection (e)(2)), and to retain records of such tests. Any records or data required under this subsection shall not be considered research data or process technology for purposes of section 14(a).

(b) REVIEW.—As soon as practicable, the Administrator shall conduct and complete a systematic and comprehensive review of the chemical substances subject to this Act, for the purpose of determining the extent to which rules under this section are warranted. A statement of the progress made toward meeting this objective shall be transmitted to the Congress by the Administrator as a part of each annual report required by section 16.

(c) APPLICABILITY.—(1) The applicability of any rule issued under this section may be limited to specified geographic areas, if there is a valid reason for such limitation in terms of the nature and extent of the risk involved.

(2) The authority of the Administrator, under subsection (a), to prescribe a rule prohibiting the manufacturing, processing, importing, or distribution in commerce of a chemical substance for a particular use or other distribution in commerce includes the authority to prohibit such distribution for a particular use in a concentration in excess of the level specified in such rule.

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(3) Rules limiting the amount of a chemical substance which may be manufactured, processed, imported, or distributed in commerce, or limiting the quantity of such substance which may be manufactured, processed, imported, or distributed for a particular distribution or use, shall, upon the petition of any manufacturer, processor, importer, or distributor in commerce thereof, provide for assigning production, processing, and distribution quotas, to the extent necessary, with respect to the chemical substance involved. The permissible quota for each person who applies to manufacture, process, or import such substance or to engage in its distribution in commerce shall be determined in accordance with criteria which the Secretary of Commerce, in consultation with the Administrator and the Attorney General, shall prescribe by rule. Such criteria shall take into account all relevant factors, including (A) effects on competition; (B) the market shares, productive capacity, and product and raw material inventories of the precursors of the chemical substance of persons applying for quotas; (C) emergency conditions; and (D) effects on technological innovation.

(d) FACTORS.—In promulgating rules under subsection (a), the Administrator shall consider relevant factors, including—

(1) the effects of the substance on health, and the magnitude and duration of human exposure to it;

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(2) the effects of the substance on the environment, and the magnitude and duration of environmental exposure to it; and

(3) the benefits of the substance for a distribution in commerce, and the availability of less hazardous alternatives.

(e) EFFECTIVE DATE.—The Administrator shall specify the proposed effective date of any rule proposed under subsection (a). The effective date shall not be later than 6 months after the date on which any such rule is promulgated as a final rule, unless the Administrator, for good cause shown, determines that a later date is appropriate.

(f) QUALITY CONTROL OF ADULTERATED CHEMICAL SUBSTANCES.—(1) If the Administrator has good cause to believe that a particular chemical substance is being manufactured, imported, or processed in a manner which permits or causes the adulteration of such chemical substance—

(A) the Administrator shall (i) require from manufacturers, importers, or processors a detailed description of quality control procedures followed in such manufacturing, processing, or importing, and (ii) take any other actions that are authorized by this Act; and

(B) if the Administrator thereafter determines by rule that such quality control procedures are inadequate to prevent the adulteration of such chemical substance, the

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Administrator may order manufacturers, importers, or processors to revise such quality control procedures to the extent which the Administrator finds reasonable and necessary to remedy such inadequacy.

(2) As used in this subsection, a chemical substance is adulterated if it, or any precursor substance used or produced in its manufacture or processing, contains any other chemical substance or contaminant which itself, or in combination with such chemical substance, is found by the Administrator to pose or be likely to pose an unreasonable risk to human health and/or the environment.

(g) PROCEDURE.—Rules issued under subsections (a) and (f) (and amendments thereto or repeals thereof) shall be promulgated pursuant to section 553 of title 5, United States Code; except that in promulgating any such rule, amendment, or repeal (A) the Administrator shall give interested persons an opportunity for the oral presentation of data, views, or arguments, in addition to an opportunity to make written submissions; (B) a transcript shall be made of any oral presentation; and (C) the Administrator shall provide for cross-examination to such extent, and in such manner, as the Administrator, in his discretion, determines is necessary and appropriate in view of the nature of the issue involved, the number of the participants, and the nature of the interests of such participants.

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IMMINENT HAZARD

SEC. 7. (a) DEFINITION.—*An imminent hazard shall be considered to exist when the evidence is sufficient to show that the manufacturing, processing, importing, or distribution in commerce of a chemical substance, or of a product containing such substance, ~~will result in an unreasonable risk to human health and the environment~~ will present an unreasonable risk of death, severe personal injury or serious environmental harm, prior to the completion of an administrative hearing or other proceeding ~~held pursuant to this Act~~ authorized under any other section of this act.*

(b) DETERMINATION.—If the Administrator determines that an imminent hazard exists, he shall (1) petition an appropriate district court of the United States, or he may request the United States attorney for such district to do so, to restrict the manufacture, processing, importing, or distribution in commerce of the chemical substance or of the product responsible for the hazard, or to take such other action as is appropriate; ~~or (2) by suspension order issued in accordance with subsection (c), restrict the manufacturing, processing, importing, or distribution in commerce of the chemical substance or of the product responsible for the hazard. The Administrator shall, as soon as practicable, if he has not done so, propose any rule, pursuant to section 6, which may be warranted.~~

(c) SUSPENSION ORDER.—(1) Except as provided in paragraph (3), the Administrator shall publish his intent

to issue a suspension order in the Federal Register and shall notify, to the maximum extent practicable, any person against whom such an order is applicable. Such publication and notice shall include findings pertaining to the Administrator's determination that an imminent hazard exists. A person as to whom such an order is applicable shall thereafter be granted an opportunity, in accordance with the provisions of paragraph (2), for an expedited hearing before the Administrator on the question of whether an imminent hazard exists.

(2) If no request for a hearing is submitted to the Administrator within 5 days after such publication or notification to such person, the suspension order may be issued and shall take effect and shall not be subject to judicial review. If a hearing is requested, it shall commence within 5 days of the receipt of the request for a hearing, unless the person requesting such hearing and the Administrator agree that it shall commence at a later time. Within 10 days after the conclusion of any such hearing, the Administrator shall render a final order on the issue of suspension.

(3) If the Administrator determines that an emergency exists and that as a consequence thereof he is unable to comply with paragraphs (1) and (2), the Administrator shall issue a suspension order prior to the notification required under paragraph (1), in which event the procedures specified in

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paragraph (2) shall apply, except that the suspension order shall be in effect pending the expeditious completion of such procedures.

REPORTS

SEC. 8. (a) GENERAL.—(1) The Administrator shall, by rule, require any manufacturer or importer of a chemical substance other than a mixture, and may, at his discretion, require manufacturers, importers, or processors of mixtures to maintain such records and to submit such reports (annually and at more frequent intervals as prescribed) as he may reasonably require. The Administrator may require any or all of the following information:

(A) the common or trade name, the chemical identity, the molecular structure and location of manufacture of each chemical substance for which a report is required, insofar as known to the person making the report or insofar as reasonably ascertainable;

(B) the categories or proposed categories of use of each such substance, insofar as known to the person making the report, or insofar as reasonably ascertainable;

(C) reasonable estimates of the amounts of each substance manufactured, imported, or processed by such person for each such use or other distribution in commerce;

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(D) a description of any byproducts resulting from the manufacture, processing, or distribution in commerce of each such substance, insofar as known to the person making the report or insofar as reasonably ascertainable; and

(E) the number of workers exposed, or projected to be exposed, to such chemical substance during its manufacture, importation, or processing by such person, as appropriate, and the levels of exposure to such substance.

(2) As used in this subsection, the term "byproduct" means a chemical substance which is produced or results, as a consequence of the manufacture, importation, processing, or distribution in commerce of some other chemical substance.

(b) INVENTORY.—The Administrator shall compile and publish, within 150 days after the enactment of this Act, and shall periodically update, a listing of each chemical substance which any manufacturer, processor or importer reports (under this section) is manufactured, processed or imported into the United States. A chemical substance shall be included in such listing as of the earliest date (as determined by the Administrator) on which such substance was manufactured or processed in or imported into the United States.

(c) SUBMISSION.—Test data or other information required to be submitted pursuant to this Act shall be sub-

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mitted to the Administrator promptly but not later than 10 days after it becomes available. The Administrator may require the submission of preliminary and other reports during the course of any monitoring or testing.

(d) HEALTH AND SAFETY DATA.—A person who manufactures, processes, imports, or distributes in commerce a chemical substance shall maintain records of health and safety data with respect to effects alleged or shown to have been caused by such substance. Upon the receipt or development of any such data such person shall immediately transmit such data to the Administrator.

(e) HEALTH AND SAFETY STUDIES.—(1) A person who manufactures, imports, processes, or distributes in commerce any chemical substance shall report to the Administrator with respect to any such substance—

(A) a list of all health and safety studies in progress on the date of enactment of this Act, that have been conducted by or for the person and such list shall be updated by such person immediately upon the initiation of any such study after the date of enactment of this Act; and

(B) a list of all health and safety studies conducted by or for such person within the 40-year period prior to the date of enactment of this Act. Such list shall be submitted to the Administrator within 180 days after the date of enactment of this Act.

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The Administrator may require the submission of any study appearing on such lists.

(2)(A) Any person who manufactures, imports, processes, or distributes in commerce any chemical substance, or any chemical substances liability insurer, shall report to the Administrator any and all health and safety studies conducted by such person or insurer, or known to such person or insurer, which indicates that any chemical substance being manufactured, imported, processed, or distributed in commerce may have adverse effects on human health or the environment.

(B) As used in this paragraph, the term "chemical substances liability insurer" means a legally constituted and authorized entity that—

(i) has entered into a contract or agreement, or that is otherwise legally obligated, to pay or compensate any injured person for losses associated with a chemical substance subject to this Act; or

(ii) has insured a manufacturer, processor, or distributor in commerce of a chemical substance subject to this Act against risks to human health or the environment, or both, associated with any such chemical substance.

(f) COMMENTS.—Whenever the Administrator determines that such action would be necessary to assist him in carrying out his responsibilities and authorities under this

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Act, he may, by publishing a notice in the Federal Register, invite and afford all interested persons an opportunity to provide information and comment in writing respecting the health or environmental effects of a chemical substance. Such an invitation and opportunity shall not be deemed a proceeding for purposes of requiring the release of information under section 14(c)(1)(B).

EXEMPTIONS AND RELATIONSHIP TO OTHER FEDERAL LAWS

SEC. 9. (a) EXEMPTIONS.—This Act shall not apply to—

(1) any pesticide (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act) when manufactured, processed, or distributed in commerce for use as a pesticide;

(2) drugs (as such term is defined in section 201 (g) of the Federal Food, Drug, and Cosmetic Act);

(3) food (as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act, including poultry and poultry products (as defined in section 4 (e) and (f) of the Poultry Products Inspection Act), meat and meat food products (as defined in section 1(j) of the Federal Meat Inspection Act) and egg and egg products (as defined in section 4 of the Egg Products Inspection Act));

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(4) tobacco or tobacco products; and

(5) research and laboratory chemicals; except that (A) such chemical substances shall be subject to section (8)(e)(2); and (B) the Administrator may by rule include such chemicals within coverage under any other provision of this Act, in whole or in part, if he determines that such inclusion is necessary to protect against unreasonable risks to human health and the environment.

(b) ABSENCE OF AUTHORITY.—The Administrator shall have no authority under sections 5(e), 6, and 7 to take action to prevent or reduce an unreasonable risk to human health and the environment associated with the manufacture, processing, or distribution in commerce of a chemical substance or an article containing such substance—

(1) to the extent that the Administrator in his discretion determines the risk associated with such substance or article may be prevented or reduced to a sufficient extent under any Federal law administered, in whole or in part by the Administrator, unless he finds that the risk associated with such substance or such article cannot be prevented or reduced as effectively by his action under such other Federal law; and

(2) to the extent that such authority under section 5(e), 6, or 7 would duplicate the authority contained in

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any other Federal law (other than the National Environmental Policy Act of 1969) not administered in whole or in part by the Administrator, except that nothing contained herein shall prevent the Administrator from considering the full range of risks to human health and the environment in taking action under such section 5(e), 6, or 7 to prohibit the manufacture, importation, or processing of a chemical substance or in taking such other action which does not duplicate the authority contained in such other Federal law.

(c) NOTICE.—Whenever the Administrator determines that any chemical substance may pose an unreasonable risk to human health and the environment and that such risk could be prevented or reduced to a sufficient extent by actions taken under other Federal laws not administered by the Administrator, he shall transmit, and give public notice of such transmittal, any data received from manufacturers, importers, or processors, or data otherwise in his possession which is relevant to such risk, to the Federal agency, independent regulatory agency, or other instrumentality of the Federal Government which has legal authority to take action. Whenever such transmittal occurs, such Federal agency, independent regulatory agency, or other instrumentality, shall, within 180 days thereafter, or in the case of an imminent hazard, within 30 days thereafter, (1) complete such action as

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is necessary to prevent or reduce any such unreasonable risk in accordance with such other Federal law, or (2) publish in the Federal Register reasons for declining to take any such action. Nothing contained in this subsection shall (A) affect the manner in which final action is taken by such agency with respect to such risk, or (B) in any way affect the extent to which human health and the environment is to be protected under such other Federal law.

COORDINATION, CONSULTATION, AND COOPERATION

SEC. 10. (a) INTERAGENCY COORDINATING COMMITTEE.—(1) The Administrator, in cooperation with other appropriate Federal agencies, shall establish and be responsible for the continuing activities of an interagency coordinating committee. The committee shall design and coordinate an efficient and effective system for the collection, utilization and dissemination of data that are (A) submitted to the Administrator under the terms of this Act, (B) in the possession of other Federal agencies, or (C) are available to the Administrator or to other Federal agencies; and which could be useful to the Administrator, in carrying out the purposes of this Act, or useful to other Federal agencies charged with responsibility for collecting data on and regulating chemical substances. This system shall be made available for use by all Federal agencies and other interested agencies and persons who have responsibilities with respect to the regulation

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or study of chemical substances in terms of their effect on human health and the environment.

(2) The Administrator, in consultation with other appropriate Federal agencies, is authorized to make contracts and grants for the development of a data retrieval system suitable for carrying out the purposes described in paragraph (1).

(3) The interagency coordinating committee shall be responsible for coordinating the regulatory responsibilities and research activities of all Federal agencies with respect to chemical substances, in order to avoid duplication and promote efficiency: Provided, That nothing contained in this paragraph shall affect the authority of any Federal agency or the administering officers thereof. The Administrator shall report annually to the Congress on actions taken to coordinate with other Federal agencies, and on the activities of the interagency coordinating committee in carrying out its responsibilities under this subsection.

(b) CONSULTATION.—Prior to the establishment and publication of a priority list under section 4(c)(1) and the promulgation of initial criteria for data development, sections 4(b) and 4(c)(2), and from time to time thereafter, the Administrator shall solicit and consider the views of the Department of Health, Education, and Welfare, the interagency coordinating committee established under subsection

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(a)(1), and other appropriate Federal agencies with respect to the establishment and revision of such list and the promulgation of such criteria. At his discretion, the Administrator shall also solicit comments from such Department, committee, and agencies on the Administrator's other duties under this Act. The Secretary of Health, Education, and Welfare, utilizing the expertise of the National Institute of Environmental Health Sciences, the National Institute of Occupational Safety and Health, or any other agency of that Department, and any other Federal agency from which views have been solicited, shall cooperate and respond to any such solicitation received.

(c) COOPERATION OF FEDERAL AGENCIES.—Upon request by the Administrator, each Federal agency is authorized—

(1) to make its services, personnel, and facilities available (with or without reimbursement as determined by the Administrator) to the Administrator to assist him in the performance of his duties under this Act; and

(2) to furnish to the Administrator such information, data, estimates, and statistics, and to allow the Administrator access to all information in its possession as the Administrator may reasonably determine to be necessary for the performance of his duties under this Act.

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(d) RESEARCH AND MONITORING.—The Administrator shall, in consultation and cooperation with the Secretary of Health, Education, and Welfare, other Federal agencies, and the interagency coordinating committee established under section 10(a), conduct, and cause to be conducted by appropriate Federal agencies, such research and monitoring as is necessary to carry out the purposes of this Act.

EXPORTS AND IMPORTS

SEC. 11. (a) EXPORTS.—(1) This Act shall not apply to any chemical substance, or to any article containing such substance, if (A) it can be shown that such substance or article is manufactured, processed, sold, or held for sale for export from the United States (or that such substance was imported for export), unless such substance or article is, in fact, manufactured, processed, or distributed in commerce for use in the United States, and (B) such substance or article, when distributed in commerce, or any container in which it is enclosed when so distributed, bears a stamp or label stating that such chemical substance or article is intended for export; except that (A) any manufacturer, processor, or exporter of such chemical substance who, but for this section, would be subject to section 8 shall remain subject to the reporting requirements of section 8; (B) this subsection shall not apply to any such substance or article if the Administrator finds that it will, directly or indirectly, pose an unreasonable risk to health within the United States and to the environment

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of the United States; and (C) such chemical shall be subject to sections 4 and 5.

(2) If the submission of test data is required for a chemical substance under section 4 or 5, or if rules applicable to such substance, or to an article containing such substance, have been prescribed or proposed under section 5 or 6, the Administrator —

(A) shall (subject to section 14(c) or section 14(e)) furnish to the governments of the foreign nations to which he knows such substance or article is exported, or is intended to be exported, notice of the availability of the data submitted to the Administrator under section 4 or 5 concerning such chemical substance;

(B) may require warning labels to be affixed to any package containing such substance or article; and

(C) shall make available to any such government, upon request, notice of any rule applicable to such substance or article which has been prescribed or proposed by the Administrator under this Act.

(b) IMPORTS.—(1) The Secretary of the Treasury shall refuse entry into the customs territory of the United States of any chemical substance or of any article containing such a substance if such substance or article fails to conform with the requirements of this Act, or if it is otherwise prohibited pursuant to this Act from being distributed in commerce. If such a substance or article is refused entry, the Secretary of

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the Treasury shall (1) refuse delivery to the consignee and (2) cause the disposal or storage thereof if it is not exported by the consignee within 3 months from the date of receipt of notice of such refusal, under such regulations as the Secretary of the Treasury may prescribe. Notwithstanding the foregoing, the Secretary of the Treasury may deliver such substance or article to the consignee pending examination and decision in the matter, upon execution by the consignee of a bond for the amount of the full invoice value of such substance or article, together with the duty thereon, and providing for forfeiture of the full amount of such bond by the consignee on refusal to return such substance or article to the custody of such Secretary, when demanded for any cause, or for any other purpose. All charges for storage, cartage, and labor on substances or articles which are refused admission or delivery under this section shall be paid by the owner or consignee. In default of payment of such charges, they shall constitute a lien against any future entry into the United States made by such owner or consignee.

(2) The Secretary of the Treasury, after consultation with the Administrator, shall issue regulations for the administration and enforcement of paragraph (1).

REVIEW OF ADMINISTRATIVE ACTION

SEC. 12. (a) JUDICIAL REVIEW.—(1) Not later than 60 days following the promulgation of any rule or order

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under this Act or the failure to issue an order under section 5(f), any interested person may file a petition for judicial review of such rule or order with the United States Court of Appeals for the District of Columbia, or for the circuit in which such person resides or has his principal place of business. Copies of the petition shall be forthwith transmitted by the clerk of such court to the Administrator and to the Attorney General. The Administrator shall transmit to the Attorney General, who shall file in the court, the record of the proceedings on which the Administrator based his rule or order, as provided in section 2112 of title 28, United States Code. For purposes of this section, the term "record" means (A) such rule; (B) the transcript required of any oral presentation; (C) any written submission of interested parties; (D) any statement of purpose and justification required under section 14 (f); and (E) any other information which the Administrator considers relevant to such rule.

(2) If the petitioner applies to the court for leave to make additional submissions and shows to the satisfaction of the court that such additional submissions are material and that there are reasonable grounds for the petitioner's failure to make such submissions in the proceeding before the Administrator, the court may order the Administrator to provide additional opportunity to make such submissions. The Administrator may modify or set aside the rule or order involved

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by reason of the additional submissions and shall file such modified or new rule or order with the return of such additional submissions. The court shall thereafter review such new or modified rule or order.

(3)(A) Upon the filing of a petition under paragraph (1), the court shall have jurisdiction (i) to review the rule or order involved, in accordance with chapter 7 of title 5, United States Code, and (ii) to grant appropriate relief, including interim relief, as provided in such chapter, except that any rule or order promulgated by the Administrator under section 6 and reviewed under this section shall be affirmed, unless the findings required to be made under the applicable section are not supported by substantial evidence on the record as required to be developed, or as actually developed, in accordance with this Act.

(B) The judgment of the court affirming or setting aside, in whole or in part, a rule or order reviewed in accordance with this section shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification, as provided in section 1254 of title 28, United States Code.

(b) CITIZEN'S PETITIONS.—(1) Any person may petition the Administrator to commence a proceeding for the issuance, amendment, or revocation of a rule under sections 4(a), 6(a), 6(f), or 8(a), or an order under sections 5(e) or 7(b).

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(2) Such a petition shall be filed in the principal office of the Administrator and shall set forth (A) the basis for which it is claimed establish that such rule or order or an amendment or revocation thereof is necessary, and (B) a brief description of the content of the rule or order or amendment thereof which it is claimed should be issued, amended, or revoked by the Administrator.

(3) The Administrator may hold a public hearing or may conduct such investigation or proceeding as he deems appropriate in order to determine whether or not such petition should be granted.

(4) Within 120 days after the filing of a petition described in paragraph (2), the Administrator shall either grant or deny such petition. If the Administrator grants such petition, he shall promptly commence an appropriate proceeding under section 4, 6, or 7. If the Administrator denies such petition, he shall publish such denial, including the reasons therefor, in the Federal Register.

(5)(A) If the Administrator denies the petition under this section (or if he fails to grant or deny such petition within the 120-day period) the petitioner may commence a civil action in a district court of the United States to compel the Administrator to initiate a proceeding with respect to the action requested. Any such civil action shall be filed within 60 days after the Administrator's denial of the petition, or (if the Administrator fails to grant or deny the petition within 120 days

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after the filing of the petition) within 60 days after the expiration of the 120-day period.

(B) If the petitioner can demonstrate to the satisfaction of the court, by a preponderance of the evidence in a de novo proceeding before such court, that such chemical substance presents an unreasonable risk to human health and the environment, or both, the court shall order the Administrator to initiate an action to prevent such unreasonable risk.

(C) In any civil action under this subsection, the district court shall have no authority to compel the Administrator to take any action other than the initiation of a rulemaking or other proceeding under section 4, 6, or 7.

(6) The remedies under this section shall be in addition to, and not in lieu of, other remedies provided by law.

(7) Paragraphs (4) and (5) shall not become effective with respect to petitions submitted under section 4(a) until 2 years after the date of enactment of this Act.

ENFORCEMENT

SEC. 13. (a) PROHIBITED ACTS.—*It shall be unlawful for any person to—*

(1) fail or refuse to comply with any provision of sections 4, 5, or 6, or any rule or order prescribed under any of those sections or any order under section 7(b).

(2) fail or refuse to comply with section 8 or any rule or order prescribed under that section;

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(3) fail or refuse to permit access to or copying of records, fail or refuse to permit entry or inspection, or fail to take any other action required under section 14(a);

(4) fail or refuse to comply with instructions issued in accordance with a rule described in section 6(a)(3);

(5) distribute in commerce, or use for commercial purpose, a chemical substance which such person knew or had reason to know was manufactured or distributed in commerce in violation of section 5 or 6;

(6) violate any condition specified by the Administrator under section 14(c)(2); or

(7) fail or refuse to comply with any rule or regulation promulgated pursuant to this Act.

(b) PENALTIES.—(1)(A) Any person who violates a provision of subsection (a) shall be liable to the United States for a civil penalty. Each day of a continuing violation is a separate violation for purposes of this subsection. The amount of such civil penalty shall be assessed by the Administrator by written notice after completion of procedures specified under section 554 of title 5, United States Code. In determining the amount of such penalty, the Administrator shall take into account the nature, circumstances, extent, and gravity of the violation or violations and, with respect to the violator, ability to pay, effect on ability to

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continue to do business, any history of prior such violations, the degree of culpability, and such other matters as justice may require: Provided, that the amount of each penalty shall not exceed $25,000 for each such violation.

(B) Any person who is aggrieved by the assessment of a civil penalty under this subsection may appeal such decision of the Administrator by bringing a civil action against the Administrator for rescission or modification of such penalty, in the district court of the United States for the District of Columbia or for any judicial district in which he resides or transacts business, within 30 days from the date on which he is notified of such decision by certified mail. In any such judicial proceeding, the factual findings of the Administrator shall be sustained if supported by substantial evidence on the record considered as a whole.

(C) The Administrator may, in his discretion, compromise, modify, or remit, with or without conditions, any civil penalty imposed or subject to imposition under this subsection. The amount of such penalty, when finally determined, or the amount agreed upon in compromise, may be deducted from any sums owing by the United States to the person charged.

(D) If any person fails to pay an assessment of a civil penalty after it has become final and the time for appeal has run, or after the appropriate court has entered final judgment

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in favor of the Administrator, the Attorney General shall recover the amount assessed (plus interest at currently prevailing rates from such date) in any appropriate district court of the United States. In such action, the validity, amount, and appropriateness of such penalty shall not be subject to review.

(2)(A) Any person who knowingly or willfully violates any provision of subsection (a) shall, in addition to or in lieu of a civil penalty imposed under subsection (a) be liable, upon conviction, to a fine of not more than $25,000 for each day of violation, or to imprisonment for not more than 1 year, or both.

(B) As used in this paragraph the term "knowingly" means having actual knowledge.

(c) INJUNCTIONS.—(1) Upon application by the Administrator or the Attorney General, the district courts of the United States shall have jurisdiction to restrain any act prohibited under subsection (a) or to compel the taking of any action required by this Act or any rule issued thereunder.

(2)(A) The court in which an action is filed under paragraph (1) or section 7 shall have power to grant such temporary or permanent relief as may be necessary to protect human health and the environment from an unreasonable risk associated with the chemical substance involved in such action. Such relief may require (in the case of an action

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under paragraph (1) or under section 7) a mandatory order requiring (i) notification of such risk to those purchasers of such substance or of an article containing such substance who are known to the defendant; (ii) public notice; (iii) recall; and (iv) the replacement or refund of such substance or article. A manufacturer, processor, importer, or distributor in commerce of such substance or article may be required by such an order to reimburse any other person (including wholesalers, retailers, and distributors) for such other person's expenses in connection with implementing such order, if the court determines that such reimbursement would be equitable.

(B) An action under paragraph (1) or under section 7 may be maintained in the United States District Court for the District of Columbia or in the district court of the United States for any judicial district in which any of the defendants is found, resides, or transacts business. In any such action, process may be served on a defendant in any other district in which such defendant resides or may be found. Subpenas requiring attendance of witnesses in such an action may run into any other judicial district. The court shall take into account the convenience of the parties in determining the appropriate judicial district for an action under this subsection which may otherwise be brought in more than one judicial district.

(d) SEIZURE.—A chemical substance, or an article containing such a substance, which was manufactured, processed, or distributed in commerce in violation of this Act, or which is the subject of an action under section 7, shall be liable to be proceeded against by process of libel for the seizure and condemnation of such substance or article in any district court of the United States within the jurisdiction of which such substance or article is found. Such proceedings shall conform as nearly as possible to proceedings in rem in admiralty.

(e) SPECIFIC RELIEF.—In any action requesting equitable relief, under any Act administered by the Administrator, or instituted at the request of the Administrator, where a risk to human health is alleged and established, a failure by the party requesting such relief to prove that demonstrable harm to health now exists or will result, shall not, in and of itself, constitute a permissible basis upon which to deny such relief. When such risk is established, the court shall consider the probability that demonstrable harm exists or will result and the human health consequences from such harm. The preceding two sentences shall govern all proceedings in actions brought after the date of enactment of this Act and all further proceedings in actions then pending, except to the extent that in the opinion of the court their application in a particular

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action then pending would not be feasible or would work injustice.

(f) CITIZEN'S CIVIL ACTION.—(1) Except as provided in paragraph (2), any interested person may commence a civil action for injunctive relief on his own behalf—

(A) against any person (including (i) the United States, and (ii) any other governmental instrumentality or agency to the extent permitted by the eleventh amendment to the Constitution) who is alleged to be in violation of any rule or order prescribed under section 4, 5, or 6; or

(B) against the Administrator where there is alleged a failure of the Administrator to perform any act or duty under this Act which is not discretionary.

Any action under subparagraph (A) shall be brought in the district court of the United States for the district in which the alleged violation occurred. Any action brought under subparagraph (B) shall be brought in such district court for the District of Columbia, or in such district court for the judicial district in which the plaintiff is domiciled. The district courts shall have jurisdiction over suits brought under this section, without regard to the amount in controversy or the citizenship of the parties.

(2) No civil action may be commenced—

(A) under paragraph (1)(A)—

(i) prior to 60 days after the plaintiff h

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given notice of the alleged violation to the Administrator, and to any alleged violator of the rule or order, or

(ii) if the Administrator (or Attorney General on his behalf) has commenced and is diligently prosecuting a civil action in a court of the United States to require compliance with the rule or order: Provided, That when such action is commenced after notice has been given, any such person giving such notice may intervene as a matter of right in such action; or

(B) under paragraph (1)(B), prior to 60 days after the plaintiff has given notice of such action to the Administrator, except that such action may be brought 10 days after such notification in the case of an action under this section for an alleged failure of the Administrator to act under section 7.

Notice under this subsection shall be given in such manner as the Administrator shall prescribe by rule.

(3)(A) In any action under this section, the Administrator, if not a party, may intervene as a matter of right.

(B) The court, in issuing any final order in any action brought pursuant to paragraph (1), may award reasonable fees for attorneys and expert witnesses, whenever the court determines that such an award is appropriate.

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(C) Nothing in this section shall restrict any right which any person (or class of persons) may have under any statute or of common law to seek enforcement of any rule or order or to seek any other relief.

(D) For purposes of this subsection, the term "person" means an individual, corporation, partnership, association, State, municipality, or political subdivision of a State.

(4) When actions brought under paragraph (1)(A) involving the same defendant and the same issues or violations are pending in two or more jurisdictions, such pending proceedings, upon application of the defendant reasonably made to the court of one such jurisdiction, may, if the court in its discretion so decides, be consolidated for trial by order of such court. If no order for consolidation is so made within a reasonable time, the defendant may apply to the court of one such jurisdiction, and such court (after giving all parties reasonable notice and opportunity to be heard) may by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the applicant's principal place of business, in which all such pending proceedings shall be consolidated for trial and tried. Such order of consolidation shall not apply so as to require the removal of any case the date for trial of which has been fixed. The court granting such order shall give prompt notification thereof to the other courts having jurisdiction of the cases covered thereby.

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ADMINISTRATIVE PROVISIONS

SEC. 14. (a) INSPECTIONS.—*The Administrator may authorize any officer, employee, or agent to enter upon, inspect, and examine at reasonable times and in a reasonable manner the records and properties of persons to the extent that such records and properties relate to the manufacturing, processing, importing, or distribution in commerce of a chemical substance, or an article containing such substance, subject to this Act. Any such officer, employee, or agent shall, upon request, display proper credentials. Unless the owner, operator, or agent in charge of such records and properties so consents in writing, no inspection authorized by this section shall extend to (1) financial data other than that relating to the costs of data development under section (4) or (5); (2) sales data other than shipments data including information relating to quantities and destinations; (3) pricing data; (4) personnel data other than job assignments, work history of production workers, and curricula vitae of individuals responsible for developing data under section 4; (5) research data (other than data required by this Act); or (6) process technology (other than information relating to the authority of the Administrator under section 6).*

(b) SUBPOENA POWER.—*In carrying out his duties under the provisions of this Act, the Administrator may by subpoena require the attendance and testimony of witnesses and*

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the production of reports, papers, documents, answers to questions, or other information that the Administrator deems advisable in carrying out his functions under this Act. Witnesses shall be paid the same fees and mileage that are paid witnesses in the courts of the United States. In the event of contumacy, failure, or refusal of any person to obey any such order, any district court of the United States in which venue is proper shall have jurisdiction to order any such person to comply therewith. The failure to obey such order of the Court is punishable by the Court as a contempt thereof.

(c) CONFIDENTIALITY.—*(1) Any information reported to, or otherwise obtained by, the Administrator or his representative, under this Act, which is a trade secret or another confidential matter referred to in section 1905 of title 18, United States Code, which if disclosed would result in significant competitive damage, shall be considered confidential and shall not be disclosed; except that such information may be disclosed—*

delete

(A) to officers or employees of the United States, where necessary in the performance of their official duties.

(B) when relevant in any proceeding under this Act, except that disclosure in such a proceeding shall be made in such manner as to preserve confidentiality to the extent practicable without impairing the proceeding, or

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(C) to the extent that the Administrator deter-

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mines it is necessary to protect human health and the environment.

(2) Notwithstanding any limitations contained in subsection (a) or any other provision of law, all information reported to or otherwise obtained by the Administrator or his representative shall be made available, upon request to qualified scientists under conditions specified by the Administrator to ensure that release of such information will not result in significant competitive damage to the originator of the information.

(3) Notwithstanding any limitation contained in subsection (a) or in any other provision of law, all information reported to or otherwise obtained by the Administrator or his representative shall be made available upon request of any duly authorized committee of the Congress.

(4) Names of individuals maintained in records pertaining to health and safety data shall only be made public after written permission is obtained by the Administrator from the individuals in question. The confidentiality of medical records shall be maintained insofar as it is reasonable and appropriate for purposes of this Act.

(5) Not less than 30 days prior to the public disclosure of any information obtained from any person under this Act, or the disclosure of such information to qualified scientists under paragraph (2) (other than any disclosure under para-

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graph (1) (A) or (B) or paragraph (3)), which is designated by such person to be a trade secret or other confidential matter referred to in section 1905 of title 18, United States Code, the Administrator shall, to the extent practicable, notify and provide a summary of the information to be disclosed to the person from which such information was obtained. The Administrator shall provide such person a reasonable opportunity to submit comments to the Administrator with respect to the release of such information. The Administrator shall take all reasonable steps to assure, prior to the disclosure of such information, that the prohibitions contained in paragraph (1) shall not be violated.

(d) ASSISTANT ADMINISTRATOR.—The President, by and with the advice and consent of the Senate, shall appoint an Assistant Administrator for Toxic Substances of the Environmental Protection Agency. Such assistant administrator shall be a qualified individual who is, by reason of background and experience, especially qualified to direct a program concerning the effects of chemicals on human health and the environment. Such Assistant Administrator shall be responsible for the collection of data, the preparation of studies, and the making of recommendations to the Administrator for regulatory and other actions to carry out the purposes, and to facilitate the administration, of this Act.

(e) NATIONAL DEFENSE WAIVER.—The Administra-

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tor shall waive compliance with any provision of this Act upon the request of the Secretary of Defense, and upon a determination by the President that the requested waiver is necessary in the interest of national defense. The Administrator shall maintain a written record of the basis upon which such waiver was granted and shall make such record available for in camera examination when relevant in a judicial proceeding under this Act. Upon the issuance of such a waiver, the Administrator shall publish in the Federal Register a notice that the waiver was granted for national defense purposes, unless, upon the request of the Secretary of Defense, the Administrator omits such publication because the Administrator determines that such publication would be contrary to the interests of national defense, in which event the Administrator shall submit notice thereof to the Armed Services Committee of the Senate and of the House of Representatives.

(f) STATEMENT OF PURPOSE AND JUSTIFICATION.—Any proposed or final rule or order issued under this Act shall be accompanied by a statement of purpose and justification. Such a statement shall be considered part of the "record of the proceedings" for purposes of judicial review under section 12(a).

MISCELLANEOUS PROVISIONS

SEC. 15. (a) CATEGORIES.—Except for an action under section 6, any action which may be taken by the Admin-

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istrator under any provision of this Act, with respect to a chemical substance, may be taken with respect to a category of chemical substances or to classes of uses of chemical substances. Whenever the Administrator takes an action with respect to a category of chemical substances under any provision of this Act, any reference in this Act to a chemical substance (insofar as such reference relates to such action) shall be deemed to be a reference to each chemical substance in any such category.

(b) STATE REGULATION.—(1) Nothing in this Act shall affect the authority of any State or local government to regulate any chemical substance, or to establish and enforce standards for test protocols for chemical substances to protect human health and the environment, except that—

(A) if the Administrator prescribes, under section 6 a rule applicable to a chemical substance, a State or local government may not, after the effective date of such rule, establish or continue to enforce any different restriction of its own on the manufacture, processing, or distribution in commerce of such substance for purposes similar to those set forth in such rule, other than a total prohibition on the use or distribution of such substance within the territorial jurisdiction of such government; and

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(B) if the Administrator prescribes, under section 4, a rule applicable to a chemical substance, a State or local government may not, after the effective date of such rule impose requirements of its own applicable to such substance for purposes similar to those set forth in such rule.

(2) The Administrator may, by rule, upon the petition of any State or local government or upon his own initiative, exempt any State or local government from a prohibition in paragraph (1). Such an exemption shall be granted unless the Administrator finds that it will, because of difficulties in marketing, distribution, or other factors, result in placing an unreasonable burden upon commerce or will not result in a higher degree of protection accorded human health and/or the environment.

(c) ADVISORY COMMITTEES.—Nothing contained herein shall prevent the Administrator from establishing any advisory committee under the Federal Advisory Committee Act (Public Law 92–463, 86 Stat. 770) to provide technical advice to the Administrator with respect to his functions under this Act. No such advisory committee may be established for any other purpose.

ANNUAL REPORT

SEC. 16. The Administrator shall report to the Congress not later than March 1 of the year following the date of enact-

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ment of this Act and each year thereafter on all activities relating to, and all measures taken to implement and carry out, this Act during the preceding calendar year. Each such report shall include—

(1) a thorough appraisal, including analysis, estimates, and long-term projections, as to the relationship between chemical substances; human health and the environment; and the provisions of, and activities under, this Act;

(2) a survey and summary, in such detail as is deemed advisable, of the criteria for data development established under section 4 and of the data and other information submitted to the Administrator under this Act;

(3) a survey and summary of new chemical substances manufactured, processed, or imported, including new uses;

(4) a survey and summary of any rules promulgated under section 6; the effectiveness of such rules in protecting human health and the environment; and any enforcement measures in support thereof;

(5) a summary of outstanding problems confronting the administration of this Act, in order of priority, and a short-term and long-range plans for solving such problems and for other activities to implement the purposes of this Act; and

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(6) such recommendations for additional legislation as are deemed necessary or appropriate.

EMPLOYEE PROTECTION

SEC. 17. (a) GENERAL.—No employer may discharge any employee or otherwise discriminate against any employee with respect to his compensation, terms, conditions, or privileges of employment because the employee (or any person acting pursuant to a request of the employee) has—

(1) commenced, caused to be commenced, or is about to commence or cause to be commenced a proceeding under this Act;

(2) testified or is about to testify in any such proceeding; or

(3) assisted or participated or is about to assist or participate in any manner in such a proceeding or in any other action to carry out the purposes of this Act.

(b) REMEDY.—(1) Any employee who believes that he has been discharged or otherwise discriminated against by any person in violation of subsection (a) may, within 30 days after such alleged violation occurs, file (or have any person file on his behalf) a complaint with the Secretary of Labor (hereinafter in this section referred to as the "Secretary") alleging such discharge or discrimination. Upon receipt of such a complaint, the Secretary shall notify the person named in the complaint of the filing of the complaint.

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(2)(A) Upon receipt of a complaint filed under paragraph (1), the Secretary shall conduct an investigation of the violation alleged in the complaint. Within 30 days of the receipt of such complaint, the Secretary shall complete such investigation and shall notify in writing the complainant (and any person acting in his behalf) and the person alleged to have committed such violation of the results. Within 90 days of the receipt of such complaint the Secretary shall, unless the proceeding on the complaint is terminated by the Secretary on the basis of a settlement entered into by the Secretary and the person alleged to have committed such violation, issue an order either providing the relief prescribed by subparagraph (B) or denying the complaint. An order of the Secretary shall be made on the record after notice and opportunity for agency hearing. The Secretary may not enter into a settlement terminating a proceeding on a complaint without the participation and consent of the complainant.

(B) If in response to a complaint filed under paragraph (1) the Secretary determines that a violation of subsection (a) has occurred, the Secretary shall order the person who committed such violation to take affirmative action to abate the violation, as the Secretary deems appropriate, including requiring (i) such person to reinstate the complainant to his former position together with the compensation (includ-

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ing back pay), terms, conditions, and privileges of his employment, (ii) compensatory damages, and (iii) where appropriate, exemplary damages. If such an order is issued, the Secretary, at the request of the complainant, shall assess against the person against whom the order is issued a sum equal to the aggregate amount of all costs and expenses (including attorney's fees) reasonably incurred, as determined by the Secretary, by the complainant for, or in connection with, the bringing of the complaint upon which the order was issued.

(c) REVIEW.—(1) Any person adversely affected or aggrieved by an order issued under subsection (b) may obtain review of the order in the United States Court of Appeals for the circuit in which the violation, with respect to which the order was issued, allegedly occurred. The petition for review must be filed within 60 days from the issuance of the Secretary's order. The commencement of proceedings under this subparagraph shall not, unless ordered by the court, operate as a stay of the Secretary's order.

(2) An order of the Secretary, with respect to which review could have been obtained under paragraph (1), shall not be subject to judicial review in any criminal or other civil proceeding.

(d) ENFORCEMENT.—(1) Whenever a person has failed to comply with an order issued under subsection (b)(2),

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the Secretary shall file a civil action in the United States district court for the district in which the violation was found to occur to enforce such order. In actions brought under this subsection, the district courts shall have jurisdiction to grant all appropriate relief including, but not limited to, injunctive relief and compensatory and exemplary damages in addition to those which may have been imposed by such order of the Secretary. Civil actions filed under this subsection shall be heard and decided expeditiously.

(e) ORDERS.—In carrying out his duties under the provisions of this section, the Secretary of Labor may order the attendance and testimony of witnesses and the production of reports, papers, documents, answers to questions, or other information that he deems advisable in carrying out his functions under this section. Witnesses shall be paid the same fees and mileage that are paid witnesses in the courts of the United States. In the event of contumacy, failure, or refusal of any person to obey any such order, any district court of the United States in which venue is proper shall have jurisdiction to order any such person to comply therewith. The failure to obey such order of the Court is punishable by the Court as a contempt thereof.

(f) EMPLOYMENT EFFECTS.—(1) The Administrator shall conduct continuing evaluations of the potential loss or shifts of employment which may result from the issuance of

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any rule or order under this Act, including, where appropriate, investigating threatened plant closures or reductions in employment allegedly resulting from such rule or order.

(2) Any employee who is discharged or whose employment is otherwise interrupted, or is threatened with discharge or such interruption, or otherwise discriminated against by any person because of the results of any rule or order issued under this Act, or a representative of such employee, may request the Administrator to conduct a full investigation of the matter. The Administrator shall thereupon investigate the matter and, at the request of any interested party, shall hold a public hearing on not less than 5 days' notice, and shall at such hearings require the parties, including the employer involved, to present information relating to the actual or potential effect of such rule or order on employment and on any alleged discharge, interruption of employment, or other discrimination and the detailed reasons or justification therefor. Any such hearing shall be of record and shall be conducted in accordance with section 554 of title V, United States Code.

(3) Upon receiving the report of any such investigation, the Administrator shall make findings of fact as to the effect of such rule or order on employment and the alleged discharge, interruption of employment, or discrimination and shall make such recommendations as he deems appropriate.

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Such report, findings, and recommendations shall be available to the public.

(4) Nothing in this subsection shall be construed to require the Administrator to modify or withdraw any rule or order issued under this Act.

AUTHORIZATION FOR APPROPRIATIONS, FEES, AND CONGRESSIONAL RELATIONS

SEC. 18. (a) AUTHORIZATION.—There is authorized to be appropriated to the Administrator, for purposes of carrying out this Act, not to exceed $11,100,000 for the fiscal year ending June 30, 1976, not to exceed $2,600,000 for the transitional quarter ending September 30, 1976, and not to exceed $10,100,000 for the fiscal year ending September 30, 1977. No part of the funds so authorized to be appropriated shall be used to construct any research laboratories.

(b) FEES.—The Administrator may, by rule, require the payment of a reasonable fee from any person required to submit information under sections 4 and 5 to defray the cost of administering this Act. Such rules shall not provide for any fee in excess of $2,500. In setting such a fee, the Administrator shall take into account the ability to pay of the person required to submit the data and the cost of the Administrator of reviewing such data. Such rules may provide for sharing such a fee, in any case in which the expenses of testing are shared under section 4(d).

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(c) CONGRESSIONAL RELATIONS.—Whenever the Administrator submits, in connection with this Act, any budget requests, supplemental budget estimates, legislative recommendations, prepared testimony for congressional hearings, or comments on legislation to the President or to the Office of Management and Budget, he shall concurrently transmit a copy thereof to the Congress. No officer or agency of the United States shall have any authority to require the Administrator to submit budget requests or estimates, legislative recommendations, prepared testimony for congressional hearings, or comments on legislation relating to this Act to any officer or agency of the United States for approval, comments, or review, prior to the submission of such recommendations, testimony, or comments to the Congress.

Amend the title so as to read: "A bill to regulate commerce and protect human health and the environment by requiring data development, and for other purposes."

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